# UK Study of magnetic resonance imaging (MRI) for breast screening

Submission date Recruitment status Prospectively registered 18/06/2010 No longer recruiting [ ] Protocol [ ] Statistical analysis plan Registration date Overall study status 18/06/2010 Completed [X] Results Individual participant data **Last Edited** Condition category 27/11/2015 Cancer

#### Plain English summary of protocol

Not provided at time of registration

# **Contact information**

#### Type(s)

Scientific

#### Contact name

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# Additional identifiers

#### Protocol serial number

850; G9600413

# Study information

#### Scientific Title

National multicentre study of magnetic resonance imaging (MRI) as a method of screening for breast cancer in women at genetic risk

#### **Acronym**

**MARIBS** 

#### **Study objectives**

This is a national multicentre study of magnetic resonance imaging (MRI) as a method of screening for breast cancer in women at genetic risk. The study was developed in response to an invitation from the MRC in the UK to address Priority L of the NHS R and D Priorities in Cancer. The sensitivity and specificity of contrast enhanced MRI will be compared with two-view X-ray mammography in a comparative trial.

Approximately 500 women below the age of 50 at high genetic risk of breast cancer will be recruited per year for three years, with annual MRI and X-ray examination continuing for up to five years. A symptomatic cohort will be measured in the first year to establish common criteria for scoring and to ensure consistent practice. Women will be followed up to ascertain the true rate of breast cancer. The MRI examination will comprise an initial high sensitivity screening measurement, followed by a high specificity dynamic measurement in equivocal cases.

In addition to morphological assessment, the kinetics of contrast agent uptake will be measured, and quantitative pharmacokinetic parameters will be derived, to allow the most specific indicators of malignancy to be identified for subsequent routine use. Mammography, localisation, pathology and cytology will be performed in accordance with the NHS Breast Screening Programme quality assurance standards. Similar standards of quality assurance will be applied for MRI measurements and evaluation. The psychological impact and health economics of screening with both modalities in this high-risk group will be ascertained.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

North Thames Multi-centre Research Ethics Committee approved on the 11th November 1998 (ref: MREC/98/2/38)

#### Study design

Multicentre non-randomised observational screening genetic epidemiology study

### Primary study design

Observational

#### Study type(s)

Diagnostic

#### Health condition(s) or problem(s) studied

Topic: National Cancer Research Network; Subtopic: Breast Cancer; Disease: Breast

#### **Interventions**

A symptomatic cohort will be measured in the first year to establish common criteria for scoring and to ensure consistent practice. Women will be followed up to ascertain the true rate of breast cancer. The MRI examination will comprise an initial high sensitivity screening measurement, followed by a high specificity dynamic measurement in equivocal cases. In addition to morphological assessment, the kinetics of contrast agent uptake will be measured, and quantitative pharmacokinetic parameters will be derived.

#### **Intervention Type**

Other

#### **Phase**

Phase III

#### Primary outcome(s)

Annual MRI and x-ray breast examination

#### Key secondary outcome(s))

Not provided at time of registration

#### Completion date

31/03/2003

# **Eligibility**

#### Key inclusion criteria

#### Group 1:

- 1. Women aged 35 49 years
- 2. Tested BRCA1 or BRCA2 carriers
- 3. Known mutation in first degree relative
- 4. Family history of breast and ovarian cancer (four or more relatives)

#### Group 2:

- 1. Women aged 25 49 years
- 2. Tested p53 carriers
- 3. Known mutation in a first degree relative
- 4. Family history consistent with Li Frameni syndrome

#### Participant type(s)

**Patient** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

**Not Specified** 

#### Key exclusion criteria

- 1. Previous breast cancer (including ductal carcinoma in situ [DCIS])
- 2. Terminal illness, or life expectancy of less than 5 years
- 3. Pregnancy or breast-feeding (recruitment suspended until breast-feeding has finished)
- 4. Current chemotherapy (recruitment suspended until 6 months after treatment ceases; exclusion 2, above, still applies)

#### Date of first enrolment

# Date of final enrolment 31/03/2003

# Locations

#### Countries of recruitment

**United Kingdom** 

England

Study participating centre
Section of Magnetic Resonance
Sutton
United Kingdom
SM2 5PT

# Sponsor information

#### Organisation

Medical Research Council (MRC) (UK)

#### **ROR**

https://ror.org/03x94j517

# Funder(s)

#### Funder type

Research council

#### **Funder Name**

Medical Research Council (MRC) (UK) (ref: G9600413)

#### Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

United Kingdom

#### **Funder Name**

NIHR Health Technology Assessment Programme - HTA (UK)

# **Results and Publications**

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes